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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/797,374

Applicant: Jeffrey O. PHILLIPS

Filed: March 10, 2004

Title: NOVEL SUBSTITUTED BENZIMIDAZOLE  
DOSAGE FORMS AND METHOD OF USING  
SAME

Art Unit: Unknown

Examiner: unknown

Docket No.: 04242350

Customer No.: 26565

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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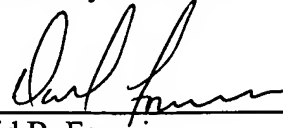
Dear Sir:

Enclosed herewith are the following for the above-captioned application:

1. Information Disclosure Statement Under 37 CFR 1.97(b);
2. Form PTO/SB08/B;
3. Box 1 including copies of listed foreign patent documents and non-literature references on Form PTO/SB08/B;
4. Box 2 including copies of listed foreign patent documents and non-literature references on Form PTO/SB08/B;
5. Return receipt postcard.

BEST AVAILABLE COPY

Respectfully submitted,



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David B. Fournier

Reg. No. 51696

Date: March 7, 2005

**MAYER, BROWN, ROWE & MAW LLP**

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Chicago, Illinois 60690-2828

Telephone: (312) 701-7989

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**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached PTO/SB/08B form. This Information Disclosure Statement is being filed before the first Office Action on the merits; and therefore the Applicant believes no fee is required.

Applicant respectfully requests that the Examiner consider the listed documents and evidence that consideration of relevant portions thereof by making appropriate notations on the attached form. Copies of the listed foreign patent documents and non-patent literature are submitted herewith in accordance with 37 CFR § 1.98(a)(2). Pursuant to MPEP 609(A)(III)A(2) (page 600-128, Rev. 2, May 2004), copies of U.S. Patent documents are not submitted as the present application was filed after June 30, 2003.

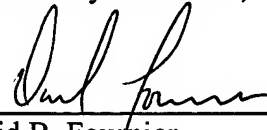
This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each of all of the listed documents are material or constitute "prior art." If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Applicant would also like to notify the Examiner that the following currently pending U.S. Patent Applications are related family members: 10/407,552, 10/418, 410, 10/641,732, 10/722,184, 10/795,860 and 10/898,135.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019.

Respectfully submitted,



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David B. Fournier

Reg. No. 51696

Date: March 7, 2005

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Facsimile: (312) 706-9000

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/797,374
Filing Date	March 10, 2004
First Named Inventor	Phillips
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	04242350

Sheet 1 22

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	4045564	08/30/77	Berntsson, et al.	
	A2	4182766	01/08/80	Krasso, et al.	
	A3	4255431	03/10/81	Junggren, et al.	
	A4	4337257	06/29/82	Junggren, et al.	
	A5	4359465	11/16/82	Ruwart	
	A6	4414216	11/08/83	Kawakita, et al.	
	A7	4472409	09/18/84	Senn-Bilfinger	
	A8	4508905	04/02/85	Junggren, et al.	
	A9	4544750	10/01/85	Brandstrom, et al.	
	A10	4620008	10/28/86	Brandstrom, et al.	
	A11	4628098	12/09/86	Nohara et al.	
	A12	4636499	01/13/87	Brandstrom, et al.	
	A13	4689333	08/25/87	Nohara et al.	
	A14	4725691	02/16/88	Brandstrom, et al.	
	A15	4738974	04/19/88	Brandstrom, et al.	
	A16	4786505	11/22/88	Lovgren, et al.	
	A17	4853230	08/01/89	Lovgren, et al.	
	A18	4965351	10/23/90	Caruso, et al.	
	A19	4985548	01/15/91	Caruso, et al.	
	A20	4990535	02/05/91	Cho et al.	
	A21	5008278	04/16/91	Brandstrom, et al.	
	A22	5013743	05/07/91	Iwahi, et al.	
	A23	5019584	05/28/91	Brandstrom, et al.	
	A24	5025024	06/18/91	Brandstrom, et al.	
	A25	5039806	08/13/91	Brandstrom, et al.	
	A26	5041442	08/20/91	Romeo et al.	
	A27	5045321	09/03/91	Makino, et al.	
	A28	5075323	12/24/91	Fain, et al.	
	A29	5093132	03/03/92	Makino, et al.	
	A30	5093342	03/03/92	Tomoi, et al.	
	A31	5106862	04/21/92	Briving, et al.	
	A32	5124158	06/23/92	Ruwart, et al.	
	A33	5215974	06/01/93	Alminger, et al.	
	A34	5219870	06/15/93	Kim	

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Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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			Art Unit	Unknown	
Examiner Name	Unknown				
Sheet	2		22	Attorney Docket Number	04242350

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		Number-Kind Code <sup>2</sup> (if known)			
	A35	5232706	08/03/93	Coll	
	A36	5244670	09/14/93	Upson, et al.	
	A37	5288506	02/22/94	Spickett, et al.	
	A38	5339700	08/23/94	Wright, et al.	
	A39	5374730	12/20/94	Slemon, et al.	
	A40	5385739	01/31/95	Debregeas, et al.	
	A41	5386032	01/31/95	Brandstrom	
	A42	5391752	02/21/95	Hoerrner, et al.	
	A43	5395323	03/07/95	Berglund	
	A44	5399700	03/21/95	Min, et al.	
	A45	5417980	05/23/95	Goldman, et al.	
	A46	5430042	07/04/95	Lindberg, et al.	
	A47	5447918	09/05/95	McCullough	
	A48	5447923	09/05/95	Castrenich, et al.	
	A49	5470983	11/28/95	Slemon, et al.	
	A50	5504082	04/02/96	Kawakita, et al.	
	A51	5589491	12/31/96	Nakanishi, et al.	
	A52	5599794	02/04/97	Eek, et al.	
	A53	5629305	05/13/97	Eek, et al.	
	A54	5633244	05/27/97	Eek, et al.	
	A55	5639478	06/17/97	Makino, et al.	
	A56	5690960	11/25/97	Bengtsson, et al.	
	A57	5693818	12/02/97	Von Unge	
	A58	5703097	12/30/97	Kim et al.	
	A59	5714504	02/03/98	Lindberg, et al.	
	A60	5714505	02/03/98	Hasselkus	
	A61	5731002	03/24/98	Olovson, et al.	
	A62	5753265	05/19/98	Bergstrand, et al.	
	A63	5766622	06/16/98	Nelson	
	A64	5776765	07/07/98	Graham, et al.	
	A65	5798120	08/25/98	Tomohisa, et al.	
	A66	5814338	09/29/98	Veronesi	
	A67	5817338	10/06/98	Bergstrand, et al.	
	A68	5840737	11/24/98	Phillips	

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			Art Unit	Unknown	
			Examiner Name	Unknown	
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		Number-Kind Code <sup>2</sup> (if known)			
	A69	5876759	03/02/99	Gowan	
	A70	5877192	03/02/99	Lindberg, et al.	
	A71	5879708	03/09/99	Makino, et al.	
	A72	5883102	03/16/99	Hamley, et al.	
	A73	5885594	03/23/99	Nilsen, et al.	
	A74	5900424	05/04/99	Kallstrom, et al.	
	A75	5929244	07/27/99	Von Unge	
	A76	5939091	08/17/99	Eoga, et al.	
	A77	5948789	09/07/99	Larsson, et al.	
	A78	5955107	09/21/99	Augello, et al.	
	A79	5958955	09/28/99	Gustavsson, et al.	
	A80	5962022	10/05/99	Bolt, et al.	
	A81	5965162	10/12/99	Fuisz, et al.	
	A82	5972389	10/26/99	Shell, et al.	
	A83	5979515	11/09/99	Olsson	
	A84	6013281	01/11/00	Lundberg, et al.	
	A85	6017560	01/25/00	Makino, et al.	
	A86	6068859	05/30/00	Curatolo et al.	
	A87	6090827	07/18/00	Erickson, et al.	
	A88	6123962	09/26/00	Makino, et al.	
	A89	6124464	09/26/00	Hogberg, et al.	
	A90	6132770	10/17/00	Lundberg	
	A91	6132771	10/17/00	Depui, et al.	
	A92	6136344	10/24/00	Depui, et al.	
	A93	6143771	11/07/00	Lindberg, et al.	
	A94	6147103	11/14/00	Anousis, et al.	
	A95	6150380	11/21/00	Lovqvist, et al.	
	A96	6162816	12/19/00	Bohlin, et al.	
	A97	6166213	12/26/00	Anousis, et al.	
	A98	6183776	02/06/01	Depui, et al.	
	A99	6248363	06/19/01	Patel et al.	
	A100	6262085	07/17/01	Whittle et al.	
	A101	6262086	07/17/01	Whittle et al.	
	A102	6268385	07/31/01	Whittle et al.	

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		Number-Kind Code <sup>2</sup> (if known)			
	A103	6274173	08/14/01	Sachs, et al.	
	A104	6280773	08/29/01	Cho et al.	
	A105	6284271	09/04/01	Lundberg, et al.	
	A106	6489346	12/03/01	Phillips	
	A107	6328993	12/11/01	Linder et al.	
	A108	2001/0053387	12/20/01	Hamied et al.	
	A109	2002/0192299	12/19/02	Taneja et al.	
	A110	6569453	04/27/03	Linder et al.	
	A111	2003/0144306	07/21/03	Phillips	
	A112	6608091	08/19/03	Whittall et al.	
	A113	6608092	08/19/03	Fujishima et al.	
	A114	6608210	08/19/03	Naka et al.	
	A115	6623759	09/23/03	Heese et al.	
	A116	2003/0181457	09/25/03	Orme et al.	
	A117	2003/0199580	10/23/03	Kishi et al.	
	A118	6645988	11/11/03	Phillips	
	A119	2003/0211147	11/13/03	Cullen et al.	
	A120	6649609	11/18/03	Teuber et al.	
	A121	2003/0215527	11/20/03	Phillips	
	A122	2003/0225136	12/04/03	Whittle et al.	
	A123	6664276	12/16/03	Fujishima et al.	
	A124	6677455	01/13/04	Kronstrom et al.	
	A125	2004/0010151	01/15/04	Finkelstein et al.	
	A126	6699885	03/02/04	Phillips	
	A127	2004/0048896	03/11/04	Phillips	
	A128	2004/0058018	03/25/04	Phillips	
	A129	5703097	12/30/97	Kim et al.	
	A130	6280773	08/29/01	Cho et al.	

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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
	B1	CA 1234118	03/15/88		
	B2	DK 19752843	07/01/99	(missing)	

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	B3	GB 2189698	11/04/87			
	B4	EP 0005129	10/31/79			
	B5	EP 0040639	12/02/81			
	B6	EP 0244380	11/04/87			
	B7	EP 0247983	12/02/87			
	B8	EP 0308515	03/29/89			
	B9	EP 0315964	05/17/89			
	B10	EP 0394471	10/31/90			
	B11	EP 0414847	03/06/91			
	B12	EP 0436620	07/17/91			
	B13	EP 0452697	10/23/91			
	B14	EP 0465254	01/08/92			
	B15	EP 0237200	07/01/92			
	B16	EP 0496437	07/29/92			
	B17	EP 0502556	09/09/92			
	B18	EP 0338861	01/20/93			
	B19	EP 0248634	07/21/93			
	B20	EP 0565210	10/13/93			
	B21	EP 0567201	10/27/93			
	B22	EP 0567643	11/03/93			
	B23	EP 0587659	03/23/94			
	B24	EP 0636364	02/01/95			
	B25	EP 0652751	05/17/95			
	B26	EP 0654471	05/24/95			
	B27	EP 0696921	02/21/96			
	B28	EP 0670160	07/14/99			
	B29	EP 1004305	05/21/00			
	B30	EP 1043977	10/22/03	(see WO 99/32093)		
	B31	EP 1375497	01/02/04			
	B32	ES 2024993	12/31/90			
	B33	JP 48 103567	12/25/73			
	B34	JP 49 005967	01/19/74			
	B35	JP 49 013172	02/05/74			
	B36	JP 49 020173	02/22/74			

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			Application Number	10/797,374	
			Filing Date	March 10, 2004	
			First Named Inventor	Phillips	
			Art Unit	Unknown	
			Examiner Name	Unknown	
Sheet	6		22	Attorney Docket Number	04242350

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Lines, Where Relevant Passages or Relevant Figures Appear	Columns, Where Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B37	JP 49 020174	02/22/74			
	B38	JP 49 041198	07/11/74			
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	B40	JP 49 095997	09/11/74			
	B41	JP 50 052065	05/09/75			
	B42	JP 50 112373	09/03/75			
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	B50	JP 52 102416	08/27/77			
	B51	JP 53 059675	05/29/78			
	B52	JP 55 019211	05/24/80			
	B53	JP 56 061311	05/26/81			
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			Application Number	10/797,374
			Filing Date	March 10, 2004
			First Named Inventor	Phillips
			Art Unit	Unknown
			Examiner Name	Unknown
Sheet	7	22	Attorney Docket Number	04242350

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	B71	JP 06 092853	04/05/94			
	B72	JP 06 100449	04/12/94			
	B73	JP 07 033659	02/03/95			
	B74	JP 09 087110	03/31/97			
	B75	JP 10 017470	01/20/98			
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	B77	JP 2000212180	08/02/00			
	B78	JP 2000355540	12/26/00			
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	B80	KR 9611238	08/21/96			
	B81	KR 9611390	08/22/96			
	B82	RO 88351	04/30/86			
	B83	WO 8900566	01/26/89			
	B84	WO 9003184	04/05/90			
	B85	WO 9009175	08/23/90			
	B86	WO 9204898	04/02/92			
	B87	WO 9208716	05/29/92			
	B88	WO 9221331	12/10/92			
	B89	WO 9305770	04/01/93			
	B90	WO 9400112	01/06/94			
	B91	WO 9402140	02/03/94			
	B92	WO 9402141	02/03/94			
	B93	WO 9501783	01/19/95			
	B94	WO 9313138	03/21/95			
	B95	WO 9507913	03/23/95			
	B96	WO 9515962	06/15/95			
	B97	WO 9523594	09/08/95			
	B98	WO 9532957	12/07/95			
	B99	WO 95/32958	12/07/95			
	B100	WO 9532959	12/07/95			
	B101	WO 9601612	01/25/96			
	B102	WO 9601622	01/25/96			
	B103	WO 9601623	01/25/96			

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		Filing Date	March 10, 2004	
		First Named Inventor	Phillips	
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	B104	WO 9601624	01/25/96			
	B105	WO 9601625	01/25/96			
	B106	WO 9602236	02/01/96			
	B107	WO 9616959	06/06/96			
	B108	WO 9624338	08/15/96			
	B109	WO 9624375	08/15/96			
	B110	WO 9638175	12/05/96			
	B111	WO 9702020	01/23/97			
	B112	WO 9702021	01/23/97			
	B113	WO 9709964	03/20/97			
	B114	WO 9725030	07/17/97			
	B115	WO 9725064	07/17/97			
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	B117	WO 9725066	07/17/97			
	B118	WO 9741114	11/06/97			
	B119	WO 9748380	12/24/97			
	B120	WO 9800114	01/08/98			
	B121	WO 9802368	01/22/98			
	B122	WO 9816228	04/23/98			
	B123	WO 9828294	07/02/98			
	B124	WO 9840054	09/17/98			
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	B135	WO 9932091	07/01/99			
	B136	WO 9932093	07/01/99			

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Sheet	10	22	Attorney Docket Number	04242350

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C1	"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp. 907-909, 1768.
	C2	"Buffered and Isotonic Solutions", <u>Physical Pharmacy</u> , Chapter 8, pp. 169-189.
	C3	ADAMS, S. P., et al., "Comments on the Report of 'association' of Omeprazole with DNA by Phillips, et al.", <u>Mutagenesis</u> , Vol. 7, No. 5, pp. 395-396 (September 1992).
	C4	AIHARA, Takeshi et al., "Pharmacological Control of Gastric Acid Secretion for the Treatment of Acid-related Peptic Disease: Past, Present, and Future", <u>Pharmacology &amp; Therapeutics</u> 98, pp. 109-127 (2003).
	C5	AL-ASSI, et al., "Treatment of Helicobacter Pylori Infection With Omeprazole-Amoxicillin Combination Therapy Versus Ranitidine/Sodium Bicarbonate-Amoxicillin", <u>The American Journal of Gastroenterology</u> , Vol. 90, No. 9, pp. 1411-14 (September 1995).
	C6	ANDERSSON, et al., "Pharmacokinetic Studies With Esomeprazole, the (S)-Isomer of Omeprazole", <u>Clinical Pharmacokinetics</u> , Vol. 40, No. 6, pp. 411-426 (2001).
	C7	ANDERSSON, T., "Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole", <u>Clin. Pharmacokinetics</u> , Vol. 31, No. 1, pp. 9-28 (July 1996).
	C8	ANDERSSON, T., et al., "Pharmacokinetics and Bioavailability of Omeprazole After Single and Repeated Oral Administration in Healthy Subjects", <u>Br. J. Clin. Pharmacol.</u> , Vol. 29, pp. 557-563 (1990).
	C9	ANDERSSON, T., et al., "Pharmacokinetics of [ <sup>14</sup> C]Omeprazole in Patients with Liver Cirrhosis", <u>Clin Pharmacokinetics</u> , Vol. 24, No. 1, pp. 71-78 (1993).
	C10	ANDERSSON, T., et al., "Pharmacokinetics of Various Single Intravenous and Oral Doses of Omeprazole", <u>European Journal of Clinical Pharmacology</u> , Vol. 39, pp. 195-197 (1990).
	C11	ARVIDSSON, et al., "Peak Distortion in the Column Liquid Chromatographic Determination of Omeprazole Dissolved in Borax Buffer", <u>Journal of Chromatography</u> , Vol. 586, Part 2, pp. 271-276 (1991).
	C12	BALABAN, D., et al., "Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients", <u>The American Journal of Gastroenterology</u> , Vol. 92, No. 1, pp. 79-83 (1997).
	C13	BALLARD, E., et al., "Bioequivalence Between Lansoprazole Sachet for Suspension and Intact Capsule," <u>Gastroenterology</u> , Vol. 120 (No. %, Suppl. 1), pg. A-245 (2001).
	C14	BALLESTEROS, et al., "Bolus or Intravenous Infusion of Rantidine: Effects on Gastric pH and Acid Secretion. A Comparison of Relative Efficacy and Cost", <u>Annals of Internal Medicine</u> , Vol. 112, No. 5, pp. 334 - 339 (1990).

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NON PATENT LITERATURE		
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	C15	BARIE & HARIRI, "Therapeutic Use of Omeprazole For Refractory Stress-Induced Gastric Mucosal Hemorrhage", <u>Critical Care Medicine</u> , Vol. 20, No. 6, pp. 899-901 (1992).
	C16	BEEKMAN, S. M., "Preparation and Properties of New Gastric Antacids I", <u>J. Pharm Assoc.</u> , Vol. 49, pp. 191-200, (1960).
	C17	Bennett & Dickson, eds., "Gastrointestinal Drugs", <u>The American Medical Association Drug Evaluation</u> , Vol. 2, The American Medical Association, Chicago, Vol 1:8.
	C18	BLUM, A., "Therapeutic Approach to Ulcer Healing," <u>The American Journal of Medicine</u> , Volume 79 (Suppl. 2C), pp.8-14 (August 30,1985)
	C19	BONE, "Let's Agree on Terminology: Definition of Sepsis", <u>Critical Care Medicine</u> , Vol. 19, No. 7, pp. 973-976 (July 1991).
	C20	BORRERO, et al., "Antacids vs. Sucralfate in Preventing Acute Gastrointestinal Tract Bleeding in Abdominal Aortic Surgery. A Randomized Trial in 50 Patients", <u>Arch. Surg.</u> , Vol. 121, pp. 810-12 (July 1986).
	C21	BRUNTON, "Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", <u>The Pharmacologic Basis of Therapeutics</u> , p. 897-913 (1990).
	C22	CANTU & KOREK, "Central Nervous System Reactions to Histamine-2 Receptor Blockers", <u>Annals of Internal Medicine</u> , Vol. 114, No. 12, pp. 1027-34 (1991).
	C23	CAOS, A., et al., "Rabeprazole for the Prevention of Pathologic and Symptomatic Relapse of Erosive or Ulcerative Gastroesophageal Reflux Disease", <u>The American Journal of Gastroenterology</u> , Vol. 95, No. 11, pp. 3081-3088 (2000).
	C24	CARROLL, M., et al., "Nasogastric Administration of Omeprazole for Control of Gastric pH" <u>10<sup>th</sup> World Congresses of Gastroenterology</u> , Abstracts (October 2-7, 1994).
	C25	CEDERBERG, C., et al., "Omeprazole: Pharmacokinetics and Metabolism in Man", <u>Scand. J. Gastroenterol.</u> , Vol. 24, Suppl. 166, pp. 33-40 (1989).
	C26	CEDERBERG, et al., "Effect of Once Daily Intravenous and Oral Omeprazole on 24-Hour Intragastric Acidity in Healthy Subjects", <u>Scand. J. Gastroenterol.</u> , Vol. 28, No. 2, pp. 179-184 (February 1993).
	C27	CHING, et al., "Antacids - Indications and Limitations", <u>Drugs</u> , Vol. 47, No. 2, pp. 305-317 (February 1994).
	C28	CIOFFI, et al., "Comparison of Acid Neutralizing and Non-acid Neutralizing Stress Ulcer Prophylaxis in Thermally Injured Patients", <u>The Journal of Trauma</u> , Vol. 36, pp. 541-47 (1994).
	C29	COOK, et al., "Nosocomial Pneumonia and the Role of Gastric pH: A Meta Analysis", <u>Chest</u> , Vol. 100, No. 1, pp. 7-13 (July 1991).

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Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			Application Number	10/797,374	
			Filing Date	March 10, 2004	
			First Named Inventor	Phillips	
			Art Unit	Unknown	
			Examiner Name	Unknown	
Sheet	12		22	Attorney Docket Number	04242350

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C30	COOK, et al., "Risk Factors For Gastrointestinal Bleeding in Critically Ill Patients. Canadian Critical Care Trial Groups", <u>The New England Journal of Medicine</u> , Vol. 330, No. 6, pp. 377-81 (February 10, 1994).
	C31	COOK, et al., "Stress Ulcer Prophylaxis in the Critically Ill: A Meta Analysis", <u>The American Journal of Medicine</u> , Vol. 91, pp. 519-527 (November 1991).
	C32	CRILL, et al., "Upper Gastrointestinal Tract Bleeding in Critically Ill Pediatric Patients", <u>Pharmacotherapy</u> , Vol. 19, No. 2, pp. 162-180 (February 1999).
	C33	CZAJA, et al., "Acute Gastrointestinal Disease After Thermal Injury: An Endoscopic Evaluation of Incidence and Natural History", <u>The New England Journal of Medicine</u> , Vol. 291, pp. 925-929 (October 31, 1974).
	C34	DEAKIN, et al., "Therapeutic Progress - Review XXXIII: Are We Making Progress In The Drug Treatment of Oesophageal Disease?", <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 13, No. 6, pp. 365-374 (December 1988).
	C35	DI IORIO, et al., "Aluminum and Phosphorus Urinary Excretion After Modifying Gastric Acid Secretion In Normal Subjects", <u>Trace Elements and Electrolytes</u> , Vol. 13, No. 1, pp. 47-49 (1996).
	C36	DIGIACINTO, et al., "Stability of Suspension Formulations of Lansoprazole and Omeprazole Stored in Amber-Colored Plastic Oral Syringes", <u>Annals of Pharmacotherapy</u> , Vol. 34, No. 5, pp. 600-605 (May 2000).
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	C38	DOBKIN, et al., "Does pH Paper Accurately Reflect Gastric pH?", <u>Critical Care Medicine</u> , Vol. 18, pp. 985-88 (September 1990).
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	C40	EISENBERG, et al., "Prospective Trial Comparing a Combination pH Probe-Nasogastric Tube With Aspirated Gastric pH in Intensive Care Unit Patients", <u>Critical Care Medicine</u> , Vol. 18, No. 10, 1092-95 (1990).
	C41	EPKE, A., et al., "Effect of Various Salts on the Stability of Lansoprazole, Omeprazole, and Pantoprazole as Determined by High-Performance Liquid Chromatography", <u>Drug Development and Industrial Pharmacy</u> , Vol. 25, No. 9, pp. 1057-1065 (1999).
	C42	FABIAN, et al., "Pneumonia and Stress Ulceration in Severely Injured Patients. A Prospective Evaluation of the Effects of Stress Ulcer Prophylaxis", <u>Arch. Surg.</u> , Vol. 128, p. 185-91 (1993).

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	C43	FELLENIOUS, et al., "Substituted Benzimidazoles Inhibit Gastric Acid Secretions by Blocking H <sup>+</sup> /K <sup>+</sup> -ATPase", <u>Nature</u> , Vol. 290, Part 5802, pp. 159-61 (1981).
	C44	FERRON et al., "Oral Bioavailability of Pantoprazole Suspended in Sodium Bicarbonate Solution", <u>Am J Health-Syst Pharm</u> , Vol. 60, pp. 1324-1328 (July 1, 2003)
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	C46	FITTON, A., et al., "Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders", <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).
	C47	FRYKLUND, et al., "Function and Structure of Parietal Cells After H <sup>+</sup> /K <sup>+</sup> -ATPase Blockade, <u>American Journal of Physiology</u> , Vol. 254, pp. G399-407 (1988).
	C48	FUCHS, C., "Antacids, Their Function, Formulation and Evaluation", <u>Drug and Cosmetic Industry</u> , Vol. 64, pp. 692-773, (1949).
	C49	GAFTER, et al., "Thrombocytopenia Associated with Hypersensitivity to Rantidine: Possible Cross-Reactivity With Cimetidine", <u>American Journal of Gastroenterology</u> , Vol. 84, No. 5, pp. 560-62 (1989).
	C50	GARNER, et al., "CDC Definitions for Nosocomial Infections", <u>American Journal Infection Control</u> , Vol. 16, No. 7, pp. 128-40 (1988).
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	C52	GRAY, et al., "Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human and Highly Purified Beef Insulins in Insulin Dependent Diabetics", <u>British Medical Journal</u> , Vol. 290, pp. 1687-91 (June 8, 1985).
	C53	HARDY, et al., "Inhibition of Gastric Secretion by Omeprazole and Efficiency of Calcium Carbonate on the Control of Hyperphosphatemia in Patients on Chronic Hemodialysis", <u>Artificial Organs</u> , Vol. 22, No. 7, pp. 569-573 (July 1998).
	C54	HATLEBAKK, J., et al., "Lansoprazole Capsules and Amoxicillin Oral Suspension in the Treatment of Peptic Ulcer Disease", <u>Scand. J. Gastroenterol.</u> , Vol. 30, No. 11, pp. 1053-57 (1995).
	C55	HEATH, et al., "Intragastric pH Measurement Using a Novel Disposable Sensor", <u>Intensive Care Medicine</u> , Vol. 14, No. 3, pp. 232-35 (1988).
	C56	HIXSON, et al., "Current Trends in the Pharmacotherapy for Gastroesophageal Reflux Disease", <u>Arch. Intern. Med.</u> , Vol. 152, No. 4, pp. 717-723 (April 1992).
	C57	HIXSON, et al., "Current Trends in the Pharmacotherapy for Peptic Ulcer Disease", <u>Arch. Intern. Med.</u> , Vol. 152, No. 4, pp. 726-732 (April 1992).

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Sheet	14	22	Attorney Docket Number	04242350

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	C58	HOLBERT, J., et al., "A Study of Antacid Buffers: I. The Time Factor in Neutralization of Gastric Acidity", <u>Journal of The American Pharmaceutical Association (Scientific Edition)</u> , Vol. 36, pp. 149-151 (1947).
	C59	HOLT, S., et al., "Omeprazole, Overview and Opinion", <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).
	C60	HORN, J., "The Proton-Pump Inhibitors: Similarities and Differences", <u>Clinical Therapeutics</u> , Vol. 22, No. 3, pp. 266-280 (2000).
	C61	HOWDEN, et al., "Oral Pharmacokinetics of Omeprazole", <u>European Journal of Clinical Pharmacology</u> , Vol. 26, pp. 641-643 (1984).
	C62	HUBER, R., "Pharmacokinetics of Pantoprazole in Man", <u>International Journal of Clinical Pharmacology and Therapeutics</u> , Vol. 34, No. 5, pp. 185-194 (1996)
	C63	HUMPHRIES, et al., "Review Article: Drug Interactions With Agents Used to Treat Acid-Related Diseases", <u>Alimentary Pharmacology &amp; Therapeutics</u> , Vol. 13, Suppl. 3, pp. 18-26 (August 1999).
	C64	JUNGnickel, P., "Pantoprazole: A New Proton Pump Inhibitor", <u>Clinical Therapeutics</u> , Vol. 22, No. 11, pp. 1268-1293 (2000).
	C65	KAROL, M. et al., "Pharmacokinetics of Lansoprazole in Hemodialysis Patients", <u>J Clin Pharmacol</u> , Vol. 35, pp. 815-820 (August 1995).
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	C67	KIILRICH, et al., "Effect of Intravenous Infusion of Omeprazole and Rantidine on Twenty-Four-Hour Intragastric pH", <u>Digestion</u> , Vol. 56, pp. 25-30 (1995).
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	C69	KROMER, "Similarities and Differences in the Properties of Substituted Benzimidazoles: A Comparison Between Pantoprazole and Related Compounds", <u>Digestion</u> , Vol. 56, No. 6, pp. 443-454 (1995).
	C70	KROMER, et al., "Differences in pH-Dependent Activation Rate of Substituted Benzimidazoles and Biological in vitro Correlates", <u>Pharmacology</u> , Vol. 56, pp. 57-70, (1998)
	C71	LAGGNER, et al., "Prevention of Upper Gastrointestinal Bleeding in Long Term Ventilated Patients", <u>American Journal of Medicine</u> , Vol. 86, Suppl. 6A, pp. 81-84 (June 9, 1989).
	C72	LANDAHL, S., et al., "Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers", <u>Clin. Pharmacokin.</u> , Vol. 23, No. 6, pp. 469-476 (1992).

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	C73	LARSON, C., et al., "Bioavailability and Efficacy of Omeprazole Given Orally and By Nasogastric Tube", <u>Digestive Diseases and Sciences</u> , Vol. 41, No. 3, pp. 475-479 (March 1996).
	C74	LARSON, et al., "Gastric Response to Severe Head Injury", <u>American Journal of Surgery</u> , Vol. 147, pp. 97-105 (January 1984).
	C75	LARSSON, et al., "Gastric Acid Antisecretory Effect of Two Different Dosage Forms of Omeprazole During Prolonged Oral Treatment in the Qastric Fistula Dog", Vol. 23, No. 8, pp. 1013-1019 (1988).
	C76	LASKY, M., et al., "A Prospective Study of Omeprazole Suspension to Prevent Clinically Significant Gastrointestinal Bleeding From Stress Ulcers in Mechanically Ventilated Trauma Patients", <u>The Journal of Trauma: Injury Infection, and Critical Care</u> , Vol. 44, No. 3, pp. 527-533 (March 1998).
	C77	LEY, B. et al., "Bioavailability of a Crushed Pantoprazole Tablet after Buffering with Sodium Hydrogencarbonate or Magaldrate Relative to the Intact Enteric Coated Pantoprazole Tablet", <u>Methods and Findings in Experimental and Clinical Pharmacology</u> , Vol. 23, pp. 41-45 (2001).
	C78	LIN, M., et al., "Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids", <u>J Formos Med Assoc</u> , Vol. 97, No. 10, pp. 704-710 (1998).
	C79	LIND, et al., "Inhibition of Basal and Betazole - and Sham-Feeding-Induced Acid Secretion by Omeprazole in Man", <u>Scand. J. Gastroenterol</u> , Vol. 21, No. 8, pp. 1004-1010 (1986).
	C80	LOCKHART, S. et al., "A Lansoprazole Suspension Formulation As An Alternative to Capsules for Oral Administration", <u>World Congresses of Gastroenterology</u> , Abstract Exh A2074 (September 6-11, 1998).
	C81	LONDONG, et al., "Dose-Response Study of Omeprazole on Meal-Stimulated Gastric-Acid Secretion and Gastrin Release", <u>Gastroenterology</u> , Vol. 85, No. 6, pp. 1373-1378 (1983).
	C82	MACONI, et al., "Prolonging Proton Pump Inhibitor-Based Anti-Helicobacter Pylori Treatment From One to Two Weeks in Duodenal Ulcer: Is It Worthwhile?", <u>Digest Liver Disease</u> , Vol. 32, pp. 275-280 (May 2000).
	C83	"Supplemental Information Disclosure Statement" as filed with U.S. Patent and Trademark Office on December 21, 2001 for U.S. Application No. 09/481,207 (U.S. Patent 6,489,346).
	C84	MARRONE & SILEN, "Pathogenesis, Diagnosis and Treatment of Acute Gastric Mucosa Lesions", <u>Clinics Gastroenterology</u> , Vol. 13, No. 2, pp. 635-50 (May 1984).
	C85	MARTIN, A., et al., <u>Physical Pharmacy - Physical Chemicals Principles in the Pharmaceutical Sciences</u> , Fourth Edition, (1993)

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	C86	MARTIN, L., et al., "Continuous Intravenous Cimetidine Decreases Stress-Related Upper Gastrointestinal Hemorrhage Without Promoting Pneumonia", <u>Critical Care Medicine</u> , Vol. 21, Vol. 1, pp. 19-30 (1993).
	C87	MARTIN, L., et al., "Stress Ulcers and Organ Failure in Intubated Patients in Surgical Intensive Care Units", <u>Ann. Surg.</u> , Vol. 215, No. 4, (April 1992).
	C88	MAXWELL, et al., "Control of Gastric pH In A Critical Care Unit: Physician Behavior and Pharmacologic Effectiveness", <u>Am. Rev. Respir. Dis.</u> , Vol. 143, No. 4 (Part 2), pg. A482 (1991).
	C89	MCANDREWS, et al., "Omeprazole and Lansoprazole Suspensions for Nasogastric Administration", <u>American Journal of Health-System Pharm.</u> , Vol. 56, pg. 81 (January 1, 1999).
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	C94	NAKAGAWA, et al., "Lansoprazole - Phase I Study of Lansoprazole (AG-1749) - Antiulcer Agent", <u>Journal of Clinical Therapeutics &amp; Medicines</u> , Vol. 7, No. 1, pp. 33-50 (1991).
	C95	NAKAMURA, M, et al., "Effect of Combined Administration of Lansoprazole and Sofalcone on Microvascular and Connective Tissue Regeneration After Ethanol-induced Mucosal Damage", <u>Journal of Clinical Gastroenterology</u> , Vol. 27, Supp. 1, pp. 170-77 (1998).
	C96	NAUNTON, M., et al., "Overuse of Proton Pump Inhibitors", <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 25, pp. 333-340 (2000).
	C97	OH & CARROLL, "Electrolyte and Acid-base Disorders", <u>The Pharmacologic Approach to the Critically Ill Patient</u> , pp. 957-68 (Chernow, B. ed. 1994).
	C98	OOSTERHUIS, et al. "Omeprazole: Pharmacology, Pharmacokinetics and Interactions", <u>Digestion</u> , Vol. 44, Suppl. 1, pp. 9-17 (1989).
	C99	OSLER, et al., "Effect of Omeprazole On The Phosphate-Binding Capacity of Calcium Carbonate", <u>Nephron</u> , Vol. 69, pp. 89-90 (1995).
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	10/797,374	
		Filing Date	March 10, 2004	
		First Named Inventor	Phillips	
		Art Unit	Unknown	
		Examiner Name	Unknown	
Sheet	17	22	Attorney Docket Number	04242350

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C101	PAUL, J., et al., "Pantoprazole Bicarbonate Suspension (PBS) Provides Oral Bioavailability Comparable To Tablet", <u>Critical Care Medicine</u> , (Feb. 2001).
	C102	PECKMAN, H., "Alternative method for administering proton-pump inhibitors through nasogastric tubes" <u>Am J Health-Syst Pharm</u> Vol. 56, pp. 1020, (May 15 1999).
	C103	PEURA & JOHNSON, "Cimetidine for Prevention and Treatment of Gastroduodenal Mucosal Lesions in Patients In an Intensive Care Unit", <u>Ann. Intern. Med.</u> , Vol. 103, pp. 173-177 (1985).
	C104	PHILLIPS, D. H., "Interaction of Omeprazole with DNA in Rat Tissues", <u>Mutagenesis</u> , Vol. 7, No. 4, pp. 277-283 (July 1992).
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	C113	PHILLIPS, J., Presentation: "From Efficacy to Effectiveness Alternative Dosing of PPI's, <u>Overview of Omeprazole Suspension</u> , (Aug 1998).
	C114	PHILLIPS, J., Presentation: "Simplified Omeprazole Suspension (SOS)", (1998).
	C115	PHILLIPS, J., Presentation: "Stress-related Mucosal Damage, Optimizing Drug Therapy, <u>Prophylaxis of Stress Ulcers</u> , (1997)

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	C116	PHILLIPS, J., Presentation: "Stress-related Mucosal Damage, Optimizing Drug therapy in the 1990's, <u>The University of Missouri Surgical Society Scientific Program</u> , (June 1994).
	C117	PHILLIPS, J., Presentation: "Update on Acid-related Disorders, Optimizing Pharmacotherapy for the 1990's, <u>A Model for Optimizing Pharmacotherapy</u> , (1996)
	C118	PHILLIPS, Project #5122: "Simplified Omeprazole Solution (S.O.S.) - Pharmacokinetic/Pharmacodynamic Study in Patients at Risk for Stress Related Mucosal Damage (SRMD)" (Approved 4/28/94).
	C119	PICKWORTH, et al., "Occurrence of Nosocomial Pneumonia in Mechanically Ventilated Trauma Patients: A Comparison of Sucralfate and Ranitidine", <u>Critical Care Medicine</u> , Vol. 21, No.12, , pp. 1856-62 (1993).
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NON PATENT LITERATURE		
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	C131	ROHAN, E., "Nasogastric Administration of Omeprazole", <u>The Australian Journal of Hospital Pharmacy</u> , Vol. 28, No. 3, pp. 174-176 (1998).
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	C144	SHARMA, V., et al., "Effect on 24-hour Intragastric Acidity of Simplified Omeprazole Solution (SOS) Administered Via Gastrostomy", <u>AJG</u> , Vol. 92, No. 9, p. 1625, Section 169 (1997).

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	C145	SHARMA, V., et al., "Simplified Lansoprazole Suspension – A Liquid Formulation of Lansoprazole – Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy", <u>The American Journal of Gastroenterology</u> , Vol. 94, No. 7, pp. 1813-1817 (July 1999).
	C146	SHARMA, V., et al., "Simplified Lansoprazole Suspension (SLS): A Proton Pump Inhibitor (PPI) In A Liquid Formulation That Works", <u>AJG</u> , p. 1647, Section 153 (September 1998).
	C147	SHARMA, V., et al., "The Effects on Intragastric Acidity of Per-Gastrostomy Administration of An Alkaline Suspension of Omeprazole", <u>Aliment Pharmacol Ther.</u> , Vol. 13, pp. 1091-1095 (1999).
	C148	SHARMA, V., "Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole", <u>American Journal of Health-System Pharmacists</u> , Vol. 56, Suppl 4, pp. S18-S21 (December 1, 1999).
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	C155	SMYTHE & ZAROWITZ, "Changing Perspectives of Stress Gastritis Prophylaxis", <u>The Annals of Pharmacotherapy</u> , Vol. 28, pp. 1073-84 (September 1994).
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	C159	TABATA, T. et al., "Stabilization of a New Antiulcer Drug (Lansoprazole) in the Solid Dosage Forms", <u>Drug Development and Industrial Pharmacy</u> , Vol. 18, pp. 1437-1447 (1992).
	C160	TAKEUCHI, et al., "Effects of Pantoprazole, A Novel H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitor, On Duodenal Ulcerogenic and Healing Responses in Rats: A Comparative Study with Omeprazole and Lansoprazole", <u>Journal of Gastroenterology and Hepatology</u> , Vol. 14, No. 3, p. 251-57 (1999).
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/797,374	
			Filing Date	March 10, 2004	
			First Named Inventor	Phillips	
			Art Unit	Unknown	
			Examiner Name	Unknown	
Sheet	22		22	Attorney Docket Number	04242350

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C173	WHIPPLE, J., et al., "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube", <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Missouri Health Sciences Library January 6, 1995].
	C174	WILDER-SMITH & MERKI, "Tolerance During Dosing with H2 Receptor Antagonists: An Overview", <u>Scand. J. Gastroenterol.</u> , Vol. 193, pp. 14-19 (1992).
	C175	YAMAKAWA, T., "Synthesis and Structure-Activity Relationships of Substituted 2-[2-imidazolylsulfinyl)methyl] Anilines As A New Class of Gastric H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitors. II.", <u>Chem Pharm Bull</u> (Tokyo), Vol. 40, No. 3, pp. 675-682 (March 1992).
	C176	YASUDA, et al., "Antacids Have No Influence on the Pharmacokinetics of Rabeprazole, A New Proton Pump Inhibitor, In Healthy Volunteers", <u>International Journal of Clinical Pharmacology and Therapeutics</u> , Vol. 37, No. 5, pp. 249-253 (1999).
	C177	ZINNER, et al., "The Prevention of Upper Gastro-Intestinal Tract Bleeding in Patients in an Intensive Care Unit", <u>Surgery, Gynecology and Obstetrics</u> , Vol. 153, pp. 214-20 (August 1981).

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